## **Prescription for Profit**

By Marcia Angell and Arnold S. Relman

Wednesday, June 20, 2001; Page A27

Few Americans appreciate the full scope and consequences of the pharmaceutical industry's hold on our health care system. Prescription drug costs are rising at an unsustainable rate -- 19 percent per year -- and will soon exceed payments to doctors as the largest item on the health bill after hospital costs.

The drug companies maintain that this is the price of success. They portray their industry as a highly risky one in a competitive market -- just able to cover its enormous research and development costs but managing nonetheless to deliver a stream of innovative drugs in the public interest.

Here are the facts. The pharmaceutical giants spend two or three times as much on marketing and administration as they do on R&D, and their profits are about twice their R&D costs. To cite a typical example, last year GlaxoSmithKline spent 37 percent of its revenues on marketing and administration and only 14 percent on R&D, while making a 28 percent profit. Overall, the pharmaceutical industry is by far the most profitable in the United States.

As for being innovative: Yes, the industry has brought important new drugs to market over the past few decades, but many of them stemmed from basic research at the National Institutes of Health or in academic laboratories supported by the NIH. Others were first developed by smaller biotech companies and then licensed to the large companies. It was recently reported that only two of Bristol-Myers Squibb's top 10 drugs were discovered in-house. Moreover, the number of innovative drugs reaching the market has actually declined in the past five years.

The pharmaceutical giants are now putting a major part of their resources into the development and marketing of "me-too" drugs -- variants of drugs already on the market. Among many examples, Claritin is one of a number of similar antihistamines; Zoloft is like many other antidepressants; and Zocor is just one of a family of cholesterol-lowering drugs. "Me-too" drugs are relatively easy to develop but require massive promotion campaigns to attract consumers to a particular brand and persuade physicians to prescribe one instead of another. Hence, the huge marketing budgets.

Far from being an exemplar of the free market, the pharmaceutical industry enjoys many government protections and subsidies. In addition to benefiting from publicly funded research, drug companies have low tax rates, because they can deduct their marketing expenses as well as their research and development costs.

Most important, their drugs enjoy 17-year (or longer) patent protection. Once a drug is patented and given a brand name, no one else may sell it, and the company is free to charge whatever the market will bear without fear of competition from generics. No wonder drug companies fight to extend the life of their patents and to obtain new patents for old drugs. That can be done merely by proposing a new use or a different dosage form, or by combining two old drugs into a single new pill. The anti-diabetes drug Glucophage XR, for example, is Bristol-Myers Squibb's newly patented once-daily replacement for the twice-daily Glucophage, whose patent expired last fall.

The drug companies devote enormous sums to promoting their interests. They have the largest lobby in Washington, and contribute copiously to political campaigns. Half the FDA's budget for the evaluation of new drugs now comes from drug company users' fees, making the agency dependent on the industry it regulates -- an obvious conflict of interest. The industry also spends lavishly to influence doctors, who write the prescriptions, and medical researchers, who test the drugs.

Last year drug companies spent more than \$8 billion and employed 83,000 sales representatives to woo doctors.

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They provided them with gifts, meals and trips, as well as another \$8 billion worth of free drug samples. The companies fund and thereby influence much of the continuing medical education doctors need to renew their licenses, and they handsomely support the scientific meetings of medical societies, where they hawk their wares and often sponsor their own programs.

The companies also want to influence researchers who test drugs in human subjects. Increasingly, they are entering into financial arrangements with academic medical centers and their faculties, arrangements that threaten the objectivity and credibility of clinical research. A growing number of drug trials are being managed by investor-owned businesses that are even more beholden to the drug companies because the companies are their only clients.

Furthermore, in their contracts with academic researchers, drug companies now often insist on controlling how the research is done and reported, and whether the results will even be published at all. Recently, there have been several widely publicized instances of drug companies suppressing research results that were not favorable to their drugs.

Prescription drugs are not like discretionary consumer products. For millions of patients, they are necessary to health and even survival. Yet, the drug companies often behave as though their only responsibility is to their shareholders.

It's time to take a hard look at the pharmaceutical industry and hold it accountable. This is particularly urgent now, given the move to add a drug benefit to Medicare. The industry would like to see such a benefit without any new regulation, but that would cause drug prices to rise even faster and hand the companies yet another windfall. Future policy on this and other matters related to prescription drugs should be based on a thorough understanding of the industry's behavior, best achieved through in-depth congressional hearings. We can't think of a more urgent investigative assignment for the Senate Committee on Health, Education, Labor and Pensions.

Marcia Angell is a senior lecturer and Arnold S. Relman is professor emeritus at Harvard Medical School. Both are former editors-in-chief of the New England Journal of Medicine.

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